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CLEVELAND, OH 44114				
EXAMINER				
TANNER, JOCELYN C				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/549,355

Applicant(s)

CARO ET AL.

Examiner

JOCELIN C. TANNER

Art Unit

4133

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2006.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-20 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 14 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 12/06/2005
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

This is in response to the application filed on July 31, 2004 in which claims 1-20 are presented for examination.

Status of Claims

Claims 1-20 are pending, of which claims 1, 9, and 12 are in independent form. Claims 1-4, 10-12, 16-19 are rejected under 35 U.S.C. 102(b). Claims 5-9, 13-15, 20-41 have been withdrawn from prosecution.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 12/06/2005 was filed after the mailing date of the application on 7/31/2004. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Objections

1. Claims 9-11 appear to be directed to an assembly of a stent and a balloon. Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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3. Regarding claim 12, it is unclear how the helix angle is defined, thus, rendering the claim vague and indefinite.
4. Regarding claim 13, it is unclear how the amplitude is measured from the centre line, thus, rendering the claim vague and indefinite.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Smith (US Patent No. 6,364,904).

6. Regarding independent claim 1, Smith discloses a stent/graft or a "stent" (FIG. 21, element #182) for insertion in a fluid conduit of the human or animal body (column 5, lines 22-23) when the stent is in a collapsed condition and for expansion to an expanded condition (column 10, lines 2-4), the stent including an outer wall for engagement with the conduit (FIG. 21), the outer wall having a planar strip or "helical portion" (FIG. 19, element #172) which in the expanded condition extends longitudinally and circumferentially through the use of a self-expanding mechanism or pulling or pushing action by user (column 8, lines 1-2), and which, upon expansion of the stent

from the collapsed condition to the expanded condition, resists extension.

7. Regarding claim 2, Smith discloses a centre line of the stent/graft or a "stent" in the expanded condition that follows a substantially helical path wherein the centre line is dependent on the shape and curves of the vasculature that the flexible and adjustable stent/graft may follow.

8. Regarding claim 3, Smith discloses a planar strip or "helical portion" including an increased amount of planar wire or "stent forming material" relative to the amount of stent forming material in portions of the stent adjacent to the helical portion (FIG. 21).

9. Regarding claim 4, Smith discloses a planar strip or "helical portion" having structural members with bent portions which resist unbending during expansion of the stent wherein the planar wire can be bonded adhesively to the planar strip (column 5, lines 63-65).

10. Regarding claim 5, Smith discloses a self-expanding stent (column 3, lines 1-2).

11. Regarding claim 6, Smith discloses a balloon expandable stent (column 3, lines 1-2).

12. Regarding claim 7, Smith discloses that in the expanded condition of the stent, the fluid conduit follows a non- planar curve as it extends in the longitudinal direction, with a curve undergoing at least one turn, wherein a flexible, adjustable stent/graft or "stent" may travel through the and accommodate irregular curves of the vascular system passageway.

13. Regarding claim 8, Smith discloses a stent graft or "stent" that expands from the collapsed condition to the expanded condition without substantial twisting (column 10, 2-5) wherein the stent expands radially in a spring-like action.

14. Claims 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al (US Patent No. 6,375,660).

Regarding independent claim 9, Fischell et al or "Fischell" herein, discloses a balloon expandable stent (FIG. 2, element #32) for insertion in a fluid conduit of the human or animal body (column 3, lines 43-44) when the stent is in a collapsed condition and for expansion to an expanded condition (column 2, 41-42), the stent including a balloon having an expandable wall, the wall having a spiral-shaped or "helical portion which in the expanded condition extends longitudinally and circumferentially when a twist is applied, and which, upon expansion of the balloon from the collapsed condition to the expanded condition, resists extension (column 3, lines 47-50).

15. Regarding claim 10, Fischell discloses a spiral-shaped or "helical portion" of the balloon expandable wall that has a wall thickness greater than that of adjacent wall portions at the folded locations of the three layers (column 3, lines 53-55).

16. Regarding claim 11, Fischell discloses an expanded condition of the stent that causes the fluid conduit to follow a non-planar curve as it extends in the longitudinal direction, the curve undergoing at least one turn, wherein a flexible, adjustable stent/graft or "stent" may travel through the and accommodate irregular curves of the vascular system passageway.

17. Claims 12 and 14-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Houston et al (EP 1254645).

Regarding independent claim 12, as best understood in light of the rejection under 35 U.S.C. 112 made in this action, Houston et al or "Houston" herein, discloses a tubing or "stent" (FIG. 3) for insertion, in a fluid conduit of the human or animal body (column 3, lines 13-14) when the stent is in a collapsed condition and for expansion to an expanded condition (column 3, lines 46-51), wherein in the expanded condition the stent causes the fluid conduit to have a flow lumen having a centre line which follows a substantially helical path, the helical centre line having a helix angle less than or equal to 65° (column 6, lines 28-31) and an amplitude less than one half of the internal diameter of the flow lumen (FIG. 3). In figure 3, Houston displays a stent in which the peak-to-center line amplitude of the center line appears to be less than one half of the

internal diameter. Houston anticipates the claimed range of less than or equal to 65° because he discloses a range of 5°-50°. A specific example in the prior art which is within a claimed range anticipates the range. MPEP 2131.03.

18. Regarding claim 14, Houston discloses a tubing or "stent" wherein the stent, in the expanded condition, is substantially free of ribs which would project into the flow lumen of the conduit as seen in figure 3 wherein the inner surface has few ridges and therefore has regions substantially free of ribs.

19. Regarding claim 15, Houston discloses helix angle is less than or equal to 15° (column 6, lines 28-31). Houston anticipates the claimed range of less than or equal to 15° because he discloses a range of 5°-50°. A specific example in the prior art which is within a claimed range anticipates the range. MPEP 2131.03.

20. Regarding claim 16, Houston discloses a flow lumen of the stented conduit having a substantially circular cross-section (column 5, line 55, FIG. 3).

21. Regarding claim 17, Houston discloses a helical centre line of the stented conduit extends over just part of the overall length of the stent in which the helical-flow inducing means that form the helical centre line may or may not extend over the entire length of the tubing (column 5, lines 1-2).

22. Regarding claim 18, Houston discloses a helical centre line of the stented conduit extends over substantially the entire length of the stent in which the helical-flow inducing means that form the helical centre line may or may not extend over the entire length of the tubing (column 5, lines 1-2).

23. Regarding claim 19, Houston discloses a centre line of the tubing or "stent" that follows a substantially helical path about an axis which is curved in which the axis curves when the tubing branches (FIG. 8).

Claim Rejections - 35 USC § 103

24. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

25. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (EP 1254645).

Regarding claim 13, as best understood in light of the rejection under 35 U.S.C. 112 made in this action, Houston discloses all of the limitations discussed in claim 12 except for the value of .05 calculated by dividing the amplitude of the helical centre line by the internal diameter of the tubing.

Houston teaches a helical centre line formed by internal ridging that has an amplitude and tubing with an internal diameter.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have provided tubing with the claimed values found by dividing the amplitude of the helical centre line by the internal diameter, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

26. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Houston et al (EP 1254645) in view of Igaki et al (US Patent No. 5,733,327).

Regarding claim 20, Houston discloses all of the limitations discussed previously in claim 12 except for a pharmaceutical coating.

Igaki et al teach coating a stent to provide locally limited and long-term dosage of drugs (column 2, line 51 and column 3, lines 19-22).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the stent, as taught by Houston, the coating or drug induced fiber, as taught by Igaki et al to provide locally limited and long-term dosage of drugs.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Hogan (US Patent No. 6,569,191), Maeda et al (US Patent No. 5,800,456) and Samson (US Patent No. 5,370,691) are related to stents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jocelin C. Tanner/
Examiner, Art Unit 4133

4/25/2008

/Frantz Coby/
Supervisory Patent Examiner
Art Unit 4133

